Drug Safety

Adverse drug reactions reported to a National HIV and Tuberculosis Health Care Worker Hotline in South Africa: description and prospective follow up of reports

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Electronic Supplementary Material 1. MIC Data Capture Forms: General queries and ADR follow-up.

GENERAL QUERY FORM MEDICINES INFORMATION CENTRE

Q#####

Name:	Address/Facility:	Taken by:	Answer provided:
Tel:		Date:	1 Immediate 4 1 - 8 hrs 2 < 30 min 5 Next day 3 30 min –1hr 6 2 - 5 days
Cell:			
Other:		Time:	

Origin:	Region:	Profession:	Topic:	HIV/AIDS/TB Sub-Topics:
1 Private Sector	01 W. Cape	01 GP/Specialist	01 ADR – other drugs	01 Adherence
2 Public Sector	02 N. Cape	02 Pharmacist	02 Availability/Supply	02 ADR – ARV/TB drugs
3 Groote Schuur	03 E. Cape	03 Intern/Student	03 Foreign Product ID	03 Dosage
	04 Gauteng	04 Nurse	04 Tablet ID	04 Failure
Contact method:	05 Mpumalanga	05 NIMART Nurse	05 Interaction	05 Initiating Therapy
1 Telephone (default)	06 Limpopo	06 Medical Aid	06 HIV/AIDS/TB	06 Interactions
2 E-mail	07 North West Prov	07 Industry	07 Lactation	07 IRIS
3 SMS / PCM	08 Free State	08 Other HCW	08 Malaria	08 Lactation
4 Other:	09 Kwazulu Natal	09 Lay Person	09 Medicolegal	09 Medicolegal
	10 Other (outside	10 Wholesaler	10 Other	10 OIs other than TB
			11 Pharmaceutical	11 Other
			12 Pharmacokinetics	12 Paediatrics
			13 Pharmacology/MOA	13 PEP
			14 Poisoning	14 Pharmacology
			15 Porphyria	15 PMTCT
			16 Pregnancy	16 Poisoning/OD
			17 Psychopharmacology	17 Porphyria
			18 Therapy	18 Pregnancy
				19 Resistance
				20 Second-line Regimen
				21 Switching Therapy
				22 TB
				23 TDF Renal ADR
				24 TDM

Demographics of the patient

***Age:** 1 ***Male** Y Pregnant

Weight: 2 ***Female** Gestation wks:

Clinical Scenario/Problem statement

Question:

Reference sources:
01 AHFS
02 Briggs
03 BNF
04 Drugdex
05 Consultant
06 Industry
07 Internet:
08 Journal
09 Martindale
10 Medline
11 Meyler's SE
12 MIMS
13 NDOH guidelines
14 Package insert
15 SAMF
16 Stockley
17 Other:

Y Clinical HIV Query

Answer:

Reply	
1	Oral – telephonic
2	Email / Fax
3	Literature supplied

Answer by	Peer reviewer
Date	Time

HIV & CURRENT REGIMEN DETAILS:

***Status**
1 Negative
2 Positive
3 Unknown

Treatment status
1 HAART (default)
2 PMTCT
3 PEP
4 Not on ARVs

Regimen
1 FDC (TDF+3TC/FTC+EFV)
6 AZT+3TC+LPV/r
4 ABC+3TC+EFV
5 ABC+3TC+LPV/r

Hepatitis B
1 Negative
2 Positive
3 Unknown

Individual drugs (other regimens):
01 ABC
02 ATV
03 AZT
04 d4T
05 EFV
06 FTC
07 LPV/r
08 NVP
09 TDF
10 3TC
11 Other:

On co-trimoxazole?
1 Yes →
2 No
3 Unknown

Date started:

Disease markers	***Date:***
CD4:	
VL:	

****Regimen start date:***

TB & CURRENT REGIMEN DETAILS:

***Status**
1 No TB
2 No TB – on prophylaxis
3 TB – on treatment
4 Unknown TB status

Type of TB
1 P-TB
2 Extra P-TB
3 DR-TB
4 XDR-TB

 # TB Episode:

Diagnosed by:
1 Gene Xpert
2 AFB
3 Culture
4 Clinical
5 Unknown

Regimen
1 RHZE
2 RH
3 INH prop.
4 Not on TB meds

Individual drugs (other regimens):
01 Amikacin
02 Capreomycin
03 Cycloserine
04 Ethambutol
05 Ethionamide
06 INH
07 Kanamycin
08 Levofloxacin
09 Moxifloxacin
10 Ofloxacin
11 PAS
12 PZA
13 RIF
14 Streptomycin
15 Terizidone
16 Other:

****Treatment start date:***

SUSPECTED ADR DETAILS:

****Short description of suspected ADR:***	****Date of onset of AE:***
Known allergies/ Previous similar reactions?	****Suspect drug(s):***

DRUG HISTORY (*PAST MONTH*) *NOT INDICATED ABOVE*

Drug & dose (& route if not per os)	***Date of first dose***	***Date of last dose***	****Indication***

INVESTIGATIONS: ***Relevant Labs***	***Date:***	***Date:***	***Date:***	***Date:***	***Date:***	***Date:***

ADR MANAGEMENT & FOLLOW-UP:

***Plan for management (select all that apply)**
1 Continue drug
2 Stop drug
3 Decrease dose
4 Substitute with:
5 Rechallenge
6 Monitor:
7 Gave information
8 Other:

***Current status of patient**
1 Out-patient
2 In-patient
3 ICU patient
4 Other:

We are following up on all patients with a suspected ADR. ****When would be appropriate to follow-up?***	Never
****Reference for the call-back*** (E.g. folder number if state hospital, age, sex and initials if private sector)	None

Query number		***Date:***
Updated status of patient 1 Out-patient 2 In-patient 3 ICU patient 4 Other:	**Actions taken** 1 Stopped drug 2 Substituted with _____ 3 Will rechallenge _____ 4 Decreased dose 5 Laboratory investigations done: _____ 6 Continued therapy 7 Antagonist given: _____ 8 Other treatment given: _____ 9 Discovered other possible cause: _____	**Patient's condition…** 1 Improved 2 Unchanged 3 Deteriorated 4 It's complicated: 5 Unknown **Needs to be called again Yes No**

Query number		***Date:***
Updated status of patient 1 Out-patient 2 In-patient 3 ICU patient 4 Other:	**Actions taken** 1 Stopped drug 2 Substituted with _____ 3 Will rechallenge _____ 4 Decreased dose 5 Laboratory investigations done: _____ 6 Continued therapy 7 Antagonist given: _____ 8 Other treatment given: _____ 9 Discovered other possible cause: _____	**Patient's condition…** 1 Improved 2 Unchanged 3 Deteriorated 4 It's complicated: 5 Unknown **Needs to be called again Yes No**